

**REMARKS**

**I. Preliminary Comments**

Applicants note, with gratitude that the previous rejection over the disclosure of Green et al., U.S. Patent 5,792,754 has now been withdrawn.

**II. Outstanding Rejections**

Claims 13-25, 36 and 37 stand rejected under 35 U.S.C. § 112 (second paragraph) as being indefinite.

Claims 13, 16-19, 22, 23, 36 and 37 remain rejected under 35 U.S.C. §102(b) as being anticipated by Brown et al. WO 96/08261.

Claims 13, 14, 16-20, 36 and 37 stand rejected under 35 U.S.C. §102(b) as being anticipated over the disclosure of Wibert et al., US 5,776,887 with Seib, US 5,855,946 for inherency.

Claims 13, 15-20, 22-25, 36 and 37 stand rejected under 35 U.S.C. § 103(a) as being obvious over Brown et al. with McNaught WO 94/14342 to support inherency

Claims 13, 14, 16-23, 36 and 37 are rejected under 35 U.S.C. §103(a) as being obvious over the disclosure of Wibert with Seib for inherency.

**III. Patentability Arguments**

**A. The Rejection Under 35 U.S.C. §112 (second paragraph) Should be Withdrawn.**

The rejection on the basis that the claims are indefinite should be withdrawn because those of ordinary skill reading the teachings of the specification would be instructed to measure resistant starch levels by practice of the method of McCleary, Proc. 42<sup>nd</sup> RACI Cereal Chem. Conf. Christchurch NZ Ed. VJ Humphrey-Taylor pp 304-312 (1992). Even if the specification had not taught use of this particular method (and it did for the reasons set

out below), those of ordinary skill would have known to use this method because it was the method recognized by the AOAC.

Submitted herewith is the Declaration of Ibrahim Abbas, Ph.D. stating that those of ordinary skill were taught by Applicants' specification that the McCleary method be used to determine resistant starch levels. Specifically, the disclosure at para. 0035 teaches:

“[0035] As used in the specification, the term ‘resistant starch’ includes those forms defined as RS1, RS2, RS3 and RS4 as defined in Brown, McNaught and Molony (1995) Food Australia 47: 272-275.”

Brown et al., Food Australia, (1995) in turn taught that “resistant starch” was defined as “the sum of starch and products of starch degradation not absorbed in the small intestine of healthy individuals” (pg. 272, col. 2 lines 8-14). Brown then cited Prosky et al., J. Assoc. Off. Anal. Chem. 71(5):1017 (1988) as providing “the officially accepted method of the Association of Analytical Chemists” for detecting resistant starch.

The Prosky method was considered the “gold standard” method for the measurement of total dietary fiber (TDF) and was designated AOAC Method 985.29. (See the accompanying Declaration of Ibrahim Abbas Ph.D and McCleary & Rossiter J. AOAC International, 87 No. 3 707-717 (2004) at. 707, col. 2 first full para.) Finally, the McCleary method of Proc. 42<sup>nd</sup> RACI Cereal Chem. Conf. Christchurch NZ Ed. VJ Humphrey-Taylor pp 304-312 (1992).

For these reasons, one of ordinary skill in the art would have been directed by the teachings in the specification to use the method of McCleary for determining resistant starch content. Moreover, the references in the application to other publications which direct use of the McCleary method merely reinforce the specific direction already provided in the

disclosure to utilize the McCleary method. The fact that other references may utilize different methods to measure resistant starch content is irrelevant where Applicants' already provided instruction as to how it should be measured for purposes of the claims.

For these reasons, the rejection under 35 U.S.C. 112 (second paragraph) should be withdrawn.

**B.     The Rejection of Claims 13, 14, 16-19, 21-23, 36 and 37 Under 35 U.S.C. §102(b) over Brown et al. WO 96/08261 Should be Withdrawn.**

The rejection of claims 13, 14, 16-19, 21-23, 36 and 37 under 35 U.S.C. §102(b), over Brown WO 96/08261 should be withdrawn because Brown does not disclose or suggest a method for regulating carbohydrate and fat metabolism comprising replacing at least 20% of the individual's daily carbohydrate intake with resistant starch and the substitution of unsaturated fat for saturated fat in the amounts and proportions recited. Specifically, each of the Brown examples includes substantial amounts of sugar or sucrose in combination with starch further diluting the resistant starch proportion of carbohydrate. Moreover, Applicants do not concede that Brown discloses a margin of error extending to 20% as the Examiner suggests. If the Examiner believes Brown teaches replacement of at least 20% than an obviousness rejection under 35 U.S.C. §103 is in order rather than a rejection under 35 U.S.C. §102. Accordingly, the anticipation rejection over Brown should be withdrawn.

**C.     The Rejection of Claims 13, 15-20, 22-25, 36 and 37 Under 35 U.S.C. §102(b) Over Wibert et al. In View of Seib et al. Should be Withdrawn.**

The anticipation rejection over Wibert in view of Seib should be withdrawn because there is no evidence that the vegetable oil blend of Wibert comprises 2 grams of unsaturated fat. The examples of Wibert only disclose the use of "vegetable oil" or a "vegetable oil blend." An examination of the specification of Wibert at cols. 3 and 4 reveals

a laundry list of vegetable and non-vegetable fats for use in Wibert's including many that are primarily saturated including coconut oil, palm kernel oil, milk fat, and egg yolk lipid. As such there is no evidence in Wibert or in Seib (which mainly teaches that high amylose starch contains amylase resistant starch) that would lead one to combine high levels of resistant starch with unsaturated fats in the manner of the invention. For these reasons, the obviousness rejection over Wibert and Seib should be withdrawn.

**D. The Rejection of Claims 13, 15-20, 22-25, 36 and 37  
Under 35 U.S.C. §103(a) over Brown WO 96/08261  
with McNaught WO 94/14342 Should be Withdrawn.**

The rejection of claims 13, 15-20, 22-25, 36 and 37 under 35 U.S.C. §103 over Brown with McNaught should be withdrawn because they fail to render the subject matter of the amended claims obvious. While Brown Table 9 discloses the use of unsaturated safflower oil the reference also discloses the use of saturated fats including hydrogenated vegetable oils and mixtures of hydrogenated and non-hydrogenated vegetable oils, such as palm oil, for a method of extrusion to produce a granular product. In response to the query from the Examiner, Brown does not teach away from the invention because it discloses an extrusion process. Brown teaches away from the invention because it teaches the use of high melting point fats such as hydrogenated oils or blends of non-hydrogenated and hydrogenated oils such as palm oil or hydrogenated maize oil. As such there is no instruction to select unsaturated fats instead of saturated fats of use in the manner of the invention and the selection of high melting point hydrogenated oils teaches away from the present invention.

Specifically, Brown teaches only that a combination of resistant starch and probiotic microorganisms can promote the growth of microorganisms in the large bowel (i.e. resistant starch functions only as a carrier and a growth medium for the microorganisms). Thus, Brown does not disclose or teach that a combination of resistant starch and unsaturated fats

when used as a replacement for a percentage of a daily intake of carbohydrates can result in the regulation of carbohydrate and fat metabolism resulting in a reduction in fat accumulation, lower plasma leptin concentration and reduced glucose and/or insulin levels.

Moreover, there is no suggestion that the subject matter described in Brown can promote a reduction in obesity and lead to enhanced sports performance. While the present claims are directed to compositions of matter and not to methods, the Action provides no reason why one of ordinary skill would be motivated to modify the compositions of the references in a manner so as to lead to the claimed compositions.

For these reasons the anticipation rejection under 35 U.S.C. §103 over Brown should be withdrawn and no new obviousness rejection under 35 U.S.C. §103 over Brown should be entered against claims 13, 15-19, 22-25, 36 and 37.

**E. The Rejection of Claims 13, 15-20, 22-25, 36 and 37 Under 35 U.S.C. §103(a) Over Wibert et al. In View of Seib et al. Should be Withdrawn**

At the outset it should be noted that the rejection over Wibert and Seib is not an anticipation rejection but one under 35 U.S.C. §103 for obviousness. The obviousness rejection over Wibert in view of Seib should be withdrawn because there is no teaching in Wibert or otherwise which instructs those of skill in the art to use the claimed resistant starch levels of the claims because only one out of eight Wibert examples disclose a proportion of resistant starch to carbohydrate greater than 20% as specified in Applicants' claims and there is no teaching in Wibert or Seib to increase the amounts of the composition to the amounts of the claims. The argument that those of ordinary skill in the art would have modified the disclosure of Wibert to "attain adequate energy requirements" so as to fall within the scope of the claims is inappropriate in the absence of some concrete teaching that the reference be so modified. The Wibert reference teaches what it teaches. To modify the Wibert disclosure so

as to fit the claims now presented requires an affirmative instruction in Wibert itself or in some other reference as to why Wibert should be so modified.

Further, the examples of Wibert do not teach the use of at least 2 g of unsaturated fat but only disclose the use of “vegetable oil” or a “vegetable oil blend.” An examination of the specification of Wibert at cols. 3 and 4 reveals a laundry list of vegetable and non-vegetable fats for use in Wibert’s compositions including many that are primarily saturated including coconut oil, palm kernel oil, milk fat, and egg yolk lipid. Accordingly, there is no teaching in Wibert or even in Seib (which mainly teaches that high amylose starch contains amylase resistant starch) that would lead one to combine high levels of resistant starch with unsaturated fats in the manner of the invention. For these reasons, the obviousness rejection over Wibert and Seib should be withdrawn.

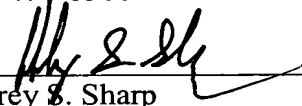
**CONCLUSION**

For all of the foregoing reasons, the rejection should now be withdrawn and a notice of allowance of all pending claims is respectfully solicited. Should the Examiner wish to discuss any issues of form or substance in order to expedite allowance of the pending application, she is invited to contact the undersigned attorney at the number indicated below.

Respectfully submitted,

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